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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,330	10/22/2003	Stuart Tugendreich	03916.0003.NPUS00	8575
23419	7590	01/25/2006	EXAMINER	
COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306			MCGILLEM, LAURA L	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/692,330	<b>Applicant(s)</b> TUGENDREICH ET AL.	
	<b>Examiner</b> Laura McGillem	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/13/2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/8/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

It is noted that Applicants have added claim 7 in the response filed 12/13/2005. Applicants have elected Group I, (claims 1-3 and 6) without traverse. Claims 4-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/13/2005. Claims 1-3 and 6-7 are pending.

### ***Priority***

It is noted that this application receives benefit of Provisional Applications No. 60/433, 069, filed 12/13/2002 and 60/420,761, filed 10/22/2002.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Applicant has not given a post office address for Inventor Michael Furness anywhere in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over applicant's signature providing a complete post office address is required.

### ***Specification***

The abstract of the disclosure is objected to because it does not sufficiently describe the invention. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The use of the trademarks GENECHIP (paragraph 0052), CODELINK (paragraph 0052 and 0062), INNOVA (paragraph 0062), GENBANK (paragraph 0067) and DRUGMATRIX (paragraph 0067) and DRUG SIGNATURES (paragraph 0068) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-3 and 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it recites the phrase "substantial fraction" and the metes and bounds of what constitutes a "substantial fraction" are not clear.

Claim 6 is vague and indefinite because it recites the phrase "deriving a test compound vector" and "derive the signature vector" and as the claim is written, it is not clear how said vectors are derived.

Claim 6 is vague and indefinite because it recites the phrase "signature vector" and it is not clear what is meant by "signature vector". Further, claim 6 recites, "projecting said test compound vector against a signature vector" and it is not clear what is meant by "projecting" a vector against a vector.

Claim 6 is vague and indefinite because it recites the phrase "test compound will exhibit" reticulocyte depletion" and it is not clear how a compound can exhibit depletion of a reticulocyte.

The closest prior art to the claimed invention appears to be U.S. Patent Application Publication No. 2002/0119462 (Mendrick et al, of record) and U.S. Patent Application Publication No. 2001/0034023 (Stanton and Zillmann).

Mendrick et al teach a method to identify changes in gene expression in cells in response to various chemicals, toxins and drugs in order to identify global changes in

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gene expression induced by said compounds (see paragraphs 0008 and 0010, for example). Mendrick et al teach this method to identify gene expression changes in response to compounds with well-characterized toxicity (see paragraphs 0012, for example). Mendrick et al teach that this method can be used for toxicity prediction by exposing a test cell population and a control cell population to a compound, measuring the levels of gene expression and comparing them to disclosed gene expression levels (see paragraphs 00053-0059, 0072-0073 and 0178, for example). Mendrick et al teach that gene expression information can be used to predict the physiological state of a tissue or cell sample after exposure to a compound or agent using statistically significant expression patterns (see paragraph 0066 and 0194, in particular). Mendrick et al do not teach that the claimed method is used to determine the propensity of a compound to cause reticulocyte depletion or that the indicator genes comprise aminolevulinate synthase 2 and peripherin.

Stanton and Zillmann teach a method to predict toxicologic or pharmacokinetic behavior of drugs in cells or patients using gene expression profiling, in order to predict a response to a treatment (see paragraphs 0014, 0052, 0315, 0427 and 0444). Stanton and Zillmann teach differential levels of gene expression that are statistically significant compared to control cells (see paragraphs 0080, 0282, 0289, 0409, 0413 and 0511, for example). Stanton and Zillmann do not teach that the claimed method is used to determine the propensity of a compound to cause reticulocyte depletion or that the indicator genes comprise aminolevulinate synthase 2 and peripherin.

**Conclusion**


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD  
1/17/2006

  
DAVID GUZO  
PRIMARY EXAMINER